

REMARKS

This is a response to the Office Action mailed July 9, 2009. Claims 1-38 and 40-51 are pending. No claims are amended herein. Reconsideration of the rejection of claims 1-51 under 35 USC §102(e) as being anticipated by Ray et al. (U.S. Pat. Appln. Pub. No. 2002/0183848) is respectfully requested in view of the inventors' Declarations under 37 C.F.R. §1.131 submitted previously and the present remarks. In addition reconsideration of the objection to the reissue declaration based on the contention that it fails to identify at least one error which is relied on is respectfully requested based on the present remarks. A Notice of Appeal accompanies this Response.

The Inventors' Declarations Under 37 CFR §1.131

The Office Action asserts that the "Declaration" filed with applicants' previous response is ineffective to overcome the Ray et al. reference because "the evidence submitted is insufficient to establish a reduction to practice of the invention ... prior to the effective date of the April 05, 1999 reference." In particular, it is asserted that, "Applicant's representative notes do not match the claimed subject matter used in the independent claims. For example, Attachment B is unreadable."

Applicants apologize for any illegibility of the Attachment B which is a page from inventor Gerald Gontarz's laboratory notebook. Attached hereto is another copy of Attachment B along with a typed transcription of Attachment B to aid in interpreting the document. The transcription was prepared by the undersigned attorney for applicants and, to the best of the undersigned's ability, is a true and accurate transcription of the handwritten laboratory notebook page (Attachment B). As discussed below, it is respectfully submitted that the Declarations of the two inventors are sufficient to show sufficient conception and reduction to practice of the claimed invention.

At page 2, third paragraph, of the Office Action, the Examiner indicates that it is unclear if the declarations are intended to show both conception and reduction to practice. However, the mere fact that an earlier paragraph in each of the Declarations refers only to conception is not inconsistent with, and does not negate, the later paragraphs explicitly asserting reduction to practice. Attention is directed to the first sentence of the third full paragraph of the Gontarz Declaration which states, “The sheets labeled “A” and “B” of my laboratory notebook clearly show conception and reduction to practice” (emphasis added). In addition, the Office Action erroneously contends that the Stoy Declaration only shows conception. The penultimate paragraph of the Stoy Declaration clearly states, “Further still, these sheets from Mr. Gontarz’s laboratory notebook reflect subject matter that I and Mr. Gontarz conceived of before April 5, 1999 and clearly demonstrate a conception and reduction to practice before the filing date of Ray” (emphasis added). It is therefore clear that both Declarations are intended to show both conception and reduction to practice.

Moreover, the attachments to both Declarations explicitly show reduction to practice of the claimed invention. Attachment A lists samples of spinal nucleus implants in accordance with the present claims by sample number in the left column and, in the right column, shows test result data relating to swelling of the sample implants in salt solution from about 2.9 times to about 4.4 times the initial volume depending on the sample. Accordingly, contrary to the assertion in the Office Action, swelling capacity of at least 25% in the claims is exemplified and referred to in both Declarations.

Attachment B describes a procedure for making a spinal nucleus implant having all the claimed features. The last sentence specifically states that the samples were saved as JG-9-107A, thus providing a clear indication that implants were in fact made according to the recited procedure. The reference to use of “aquacryl” to make a “spinal nucleus that has a shape memory” in Attachment B and the data in Attachment A disproves the assertion in the Office Action that, “it does not look like the limitations of having hydrophobic and hydrophilic material with a capacity to swell to a second height by at least 25 percent is not [sic] disclosed in the attachments.” AQUACRYL is

specifically described in applicants' specification, at column 14, lines 43- 50, in Example 1, as an "acrylic multiblock copolymer with alternating hydrophilic and hydrophobic blocks...". Thus, Attachments A and B clearly fulfill the requirement made in the last paragraph of page 2 of the Office Action for evidence of testing data and proof the device was actually built.

The Ray et al. application was filed on July 24, 2002 and was published on December 5, 2002. The Ray et al. application is a continuation of application No. 09/286,047, filed on April 5, 1999, according to the bibliographic information on the face of the published Ray et al. application. The respective Declarations of Vladimir A. Stoy and Gerald Gontarz under 37 CFR §1.131 aver that the inventors conceived of, and reduced to practice, the subject matter of the claims of the present application in the United States prior to April 5, 1999, i.e., before the earliest filing date attributable to Ray et al. The Declarations further aver that the spinal nucleus implant described in the notebook pages had preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes. The laboratory notebook pages attached to the Declarations more than adequately corroborate the averments.

Reconsideration of the refusal to accept the Declarations is respectfully requested. Since the inventors have effectively sworn behind Ray et al. it is respectfully submitted that the rejection under 35 USC §102(e) should be withdrawn.

Reissue Declaration

Page 3 of the Office Action asserts that the reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied on to support the reissue application. In particular, claims 40-51 are rejected based on a defective reissue declaration and it is contended that the "declaration correctly describes the error of inventorship in the specification but does not specifically ID any error in the claims." Applicants respectfully disagree.

A copy of the Reissue Application Declaration by the Inventor (Form PTO/SB/51 (10-05)) signed by both inventors and originally filed on April 9, 2009, is attached hereto for convenience. As can be seen, not only is inventorship addressed, but examples of subject matter recited in the specification that were not claimed are specifically identified. In particular, at page 1 of Form PTO/SB/51 (10-05), the “identification of at least one error” section states:

It is the patentee's belief that less was claimed in the patent than the patentee had the right to claim. For example, the specification discloses that the implant has a capacity to swell to a height which is greater than the height of a disc space. In addition, although disclosed in the specification, certain subject matter directed to a reinforcement element internally embedded in a spinal nucleus implant was not sufficiently claimed. Moreover, an inventor, Gerald Gontarz, was not named and should be added.

Reconsideration of requirement for a new Reissue Declaration and of the rejection of claims 40-51 is respectfully requested.

Rejection of claims 1-51 under 35 USC §102(e) based on Ray et al.

Notwithstanding the inventors' earlier conception and reduction to practice regarding the filing date of Ray et al., it is noted for the record that applicants disagree with the rejection of claims 1-51 (actually claims 1-38 and 40-51 are pending; claim 39 having been cancelled in a prior response) under 35 USC §102(e) for at least the reasons provided below.

Despite the contention in the Office Action that, “Ray et al. clearly disclose all the structural limitations claimed by all the 51 claims”, there is absolutely no citation in the Office Action to any specific passage in Ray et al. In other words, the rejection is conclusory in nature and completely unsupported. It is respectfully submitted that nowhere in Ray et al. is there a teaching or suggestion, *inter alia*, of a swellable biomimetic plastic which is capable of anisotropic expansion due to partial rehydration *in situ* into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external

pressure change to thereby increase and decrease liquid content in its hydrated state, the anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes.

Ray et al. is directed to a prosthetic spinal disc nucleus having a formed hydrogel core which is surrounded by a constraining jacket. See ¶0017. It is the constraining jacket that limits expansion of the hydrogel core. In particular, at ¶0022, for example, Ray et al. states:

The constraining jacket is flexible but substantially inelastic, having a generally fixed maximum volume that is less than a volume of the nucleus cavity. With this configuration, the constraining jacket allows the hydrogel core to transition from the streamlined shape to the wedge shape upon hydration. However, the constraining jacket limits expansion of the hydrogel core in the hydrated state. (emphasis added)

See, also, e.g., ¶0052. Accordingly, the constraining jacket conforms the hydrogel core to the dimensions of the constraining jacket upon hydration of the core. Ray et al. does not disclose or suggest an anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes as recited in independent claims 1 and 27, since it is the constraining jacket and not the hydrogel core that defines the shape of the Ray et al. hydrated implant. Moreover, Ray et al. does not disclose or suggest an implant which, *inter alia*, undergoes anisotropic expansion with a capacity to swell to a second height which is greater than the capacity of the length by at least 25% as recited in independent claim 41.

Applicants therefore do not concede that Ray et al. or US Patent No. 5,824,093 (cited but not discussed) render the present claims 1-38 and 40-51 unpatentable under 35 USC §§102(e) or 103(a) even if the accompanying §131 Declarations “swearing behind” Ray et al. were not submitted herewith.

A good faith effort has been made to place the present application in condition for allowance. If there is any point requiring discussion prior to allowance, the Examiner is earnestly solicited to telephone the undersigned attorney for Applicants at the address below.

Respectfully submitted,



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Attachments